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The Food Safety People

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Food and Drug Administration
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RE: Docket No. 2004N-0133, Electronic Records, Electronic Signatures; Public Meeting

The National Food Processors Association (NFPA) is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

The NFPA welcomes this opportunity to comment on the above referenced Electronic Records, Electronic Signatures regulation. NFPA is committed to the important goal of promoting and protecting public health and is striving to work closely with the Food and Drug Administration (FDA) as regulations are being developed to respond appropriately to security measures without undue disruption to industry operations. On behalf of the food industry members that we represent, we submit the following comments.

NFPA has had numerous discussions with the FDA, via the Industry Coalition and directly with Center for Food Safety and Nutrition (CFSAN) representatives over the past four years in order to increase the awareness of Part 11 compliance issues within the food industry. The new scope and application guidance document, published August 2003, reflects a workable approach for the food industry. NFPA members agree with the risk-based approach to compliance as it reflects the current approach used in the juice and seafood operations that employ Hazard Analysis and Critical Control Points (HACCP). We also agree with returning the focus to the predicate rule records.

The presentation, originally scheduled for June 11, 2004, that was submitted to the docket and was to be presented to the FDA Committee will be captured as part of the comments.

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Over the last seven years that the rule has been in existence, the food industry has had some basic questions that have finally been clarified.

Question 1: What is an electronic record? This was very clearly and concisely addressed in the August 2003 Guidance Document on Scope and Application under Section B.2. Definition of Part 11 Records. "The narrow interpretation now allows industry to decide if they wish to keep electronic records for regulatory decisions." In addition, the reference to the predicate rules records offered another clarification of which records shall be maintained.

Question 2: What about legacy systems? The clarification of the legacy systems for compliance answered all the food industry concerns and referenced the predicate rules. The food industry has slowly upgraded their systems but there are still many "old" units operating with procedural control to meet the intended use. This clarification alleviated a major concern and provided options for compliance without incurring a financial burden for direct replacement.

Question 3: What about validation? CFSAN representatives have spoken to the importance of validation as a good business practice and its value in demonstrating that your system is in control. NFPA has coordinated activities (two conferences in 2002/2003) with industry and government to educate and inform industry about FDA's expectations for validation. NFPA coordinated a multifunctional group, which included food processors; equipment vendors, regulatory agency, academia and NFPA staff to put together a comprehensive guideline (NFPA Bulletin 43L; Validation Guidelines for Automated Control of Food Processing Systems Used for the Processing and Packaging of Preserved Foods) designed specifically for food processing operations. The Good Automated Manufacturing Practice (GAMP) document served as a basis for the guideline. In addition, FDA's Guide to Inspections of Computerized Systems in the Food Processing Industry, 1998, also addresses validation criteria for all the predicate rules pertaining to the food segment. Since validation is already addressed in the predicate rules and other CFSAN documents, there is no need for additional regulations to outline validation criteria.

As far as the Risk Based Approach suggested in the guidance document, we agree that a risk-based approach to compliance offers many advantages as it focuses efforts and resources on the key elements of highest risk concern. The food industry has taken a risk-based approach to many regulations governing foods through the years, including the FDA's low-acid and acidified canned food regulations (Parts 113 and114) that incorporate HACCP elements in determining the critical data points and records requirements, and FDA's HACCP regulations that have been promulgated for Juice (Part 120) and Seafood products (Part 123), and USDA's meat and poultry HACCP regulations. In recent years, focus has turned to RTE refrigerated products. Given the high risk of *Listeria monocytogenes,* NFPA, academia, government and industry are conducting risk assessments using predicative modeling techniques to define the level of concern.

This allows the focus to be on the high-risk areas and away from the low risk tasks.

These are examples of processes, regulations, and guidance documents already in place in the food industry as part of our operational practices. The food industry does not see a need for a specific regulation that prescribes what to do. We urge FDA to state the intent of providing trustworthiness, authenticity, security and integrity to the records industry keeps to meet the predicate rule record requirements. This will allow advancement in technology use by allowing flexibility in how we meet FDA's intent.

In addition, NFPA does not believe a rule needs to encompass all the industry segments when there are vast differences in the operations and record keeping practices. Under current predicate rules, GMP's are written for different industry segments because they are different and have different levels of concern. For example the food industry follows 21CFR Part110, whereas the drug segment follows 21 CFR Part 210. Although we appreciate the simplicity of one rule, one size does not always fit all. If a single rule is necessary to address the use of electronic records and signatures across all regulated industries, it must general enough to permit the use of new technologies, provide risk-based flexibility and recognize differences across the industries.

The current guideline on scope and application, published August 2003, answers many of industry's questions and removes much of the confusion on electronic records. We feel that the guidance document has addressed all the outstanding questions that were of concern. The NFPA believes the rule is redundant. Most of the criteria outlined in the rule are already cited in other regulatory documents and guidelines. For example,
§11.1 and 11.2 are addressed in recent guidance; §11.3 is addressed in existing guidance and technical documents (GAMP, 43-L Bulletin, Inspections Guidelines); and §11.10, 11.30, 11.50, 11.70 are addressed in existing guidance documents and predicate rules.

Given the above, NFPA recommends that FDA rescind the current rule and suggests that each of the Centers establish guidelines specific to their industry segment. NFPA would willingly to assist in establishing these guidelines for the food industry, as was done with the 43-L Bulletin.

NFPA appreciates this opportunity to comment.

Regards,

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